

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

NOLA C. VAN DUYNE and LEO VAN DUYNE,)) Plaintiffs,)) v.)) ENCORE MEDICAL, L.P., ENCORE) ORTHOPEDICS, INC., and OSTEOIMPLANT) TECHNOLOGY, INC.,)) Defendants.))	Case No. 07 C 6857 Judge Moran Magistrate Judge Nolan
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OTI'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT

Defendant, OSTEOIMPLANT TECHNOLOGY, INC. ("OTI"), by its attorneys, ARNSTEIN & LEHR LLP, for its answer to the Complaint filed by plaintiffs, NOLA C. VAN DUYNE and LEO VAN DUYNE, state as follows:

COUNT I / PRODUCTS LIABILITY

1. That the Plaintiff, NOLA C. VAN DUYNE, presently resides at 619 Van Buren Street, Wilmington, Will County, Illinois.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 1, and therefore denies the same.

2. That the Plaintiff, LEO VAN DUYNE, is the husband of the Plaintiff, NOLA C. VAN DUYNE, and he presently resides at 619 Van Buren Street, Wilmington, Will County, Illinois.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 2, and therefore denies the same.

3. That the Defendant ENCORE MEDICAL, L.P., is a corporation with its principal place of business in Austin, Texas. This corporation manufactures, designs, assembles and sells orthopedic medical devices.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 3, and therefore denies the same.

4. That the Defendant, ENCORE ORTHOPEDICS, INC., is a corporation with its principal place of business in Austin, Texas. This corporation manufactures, designs, assembles and sells orthopedic medical devices.

ANSWER: Upon information and belief, OTI admits the allegations in Paragraph 4.

5. That the Defendant, OSTEOIMPLANT TECHNOLOGY, INC. is a corporation with its principal place of business in Baltimore, Maryland. This corporation manufactures, designs, assembles and sells orthopedic medical devices.

ANSWER: Defendant denies the allegations contained in Paragraph 5.

6. On or before November 20, 2002, the Defendants, ENCORE MEDICAL, L.P.; ENCORE ORTHOPEDICS, INC.; and OSTEOIMPLANT TECHNOLOGY, INC., acting through their agents and employees, designed, assembled, manufactured, sold and distributed an Alfa II total hip prosthesis. This was a fifty millimeter cup with three spikes and porous coating, with a twenty-eight millimeter lock polyliner with a ten degree lateral lip, a size two medial aspect stem with a thirty-eight millimeter neck.

ANSWER: OTI admits the allegations of Paragraph 6, as it relates to OTI. OTI has insufficient information or knowledge as to the truth of the remaining allegations in Paragraph 6 not directed to it, and therefore denies the same.

7. On or before November 20, 2002, the Defendants, ENCORE MEDICAL, L.P.; ENCORE ORTHOPEDICS, INC.; and OSTEOIMPLANT TECHNOLOGY, INC., acting through their agents and employees, sold or distributed to Oak Orthopedics in Kankakee, Illinois, the above mentioned Alfa II total hip prosthesis.

ANSWER: OTI has insufficient knowledge as to the truth of the allegations in Paragraph 7, and therefore denies the same.

8. On November 20, 2002, Oak Orthopedics, acting through its agent or employee, Milton J. Smit, MD, implanted the Alfa II total hip prosthesis in NOLA C. VAN DUYNE.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 8, and therefore denies the same.

9. On August 6, 2005, NOLA C VAN DUYNE was sitting on a stool, at a table, and she noticed that she could not move her right hip. She also noticed that her right foot was externally rotated. She immediately went to a local hospital, where x-rays were taken. The x-rays showed a disassociation between the femoral neck component and the stem component and the Alfa II hip prosthesis.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 9, and therefore denies the same.

10. On August 10, 2005, Dr. Milton Smith, of Oak Orthopedics, performed surgery on NOLA C. VAN DUYNE. During the surgery, Dr. Smit confirmed that the Alfa II hip prosthesis failed and that the neck had disassociated from the stem segment Dr. Smit performed a right total hip revision on NOLA C VAN DUYNE on August 10, 2005.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 10, and therefore denies the same.

11. The first time NOLA C VAN DUYNE discovered anything wrong with her Alfa II hip prosthesis was on August 6, 2005, when she experienced the pain in her right hip and notice that her right foot had been externally rotated.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 11, and therefore denies the same.

12. That the Defendants, ENCORE MEDICAL. L.P.; ENCORE ORTHOPEDICS, INC and OSTEOIMPLANT TECHNOLOGY, INC., acting through their agents and employees, should have known that the Alfa II Hip prosthesis mentioned above was in an unreasonably dangerous condition at the time it left the control of the Defendants, in that the Alfa II hip prosthesis system, especially the connecting parts between the neck and stem, and the system and parts were defective and not reasonably safe in one or more of the following respects:

- a. The Alfa II hip prosthesis, especially the connecting parts between the neck and the stem segment were defectively designed.
- b. The Alfa II hip prosthesis, especially the connecting parts between the neck and the stem segment were defectively manufactured.
- c. The Alfa II hip prosthesis, especially the connecting parts between the neck and the stem segment were defectively assembled.

ANSWER: OTI denies that the Alfa II hip prosthesis system is defective and/or not reasonably safe. Further answering, OTI denies the allegations in paragraph

12, including its subparts (a) through (c) directed to OTI. OTI has insufficient information or knowledge as to the truth of the remaining allegations in Paragraph 12 not directed to it, and therefore denies the same.

13. As a result of the above mentioned breach of the standard of practice and negligence, the Plaintiff, NOLA C. VAN DUYNE, incurred and will continue to incur unnecessary medical bills. She experienced and will continue to experience pain and suffering. She underwent unnecessary surgery.

ANSWER: OTI denies the allegations in Paragraph 13.

14. Attached hereto and made a part hereof, and incorporated herein as Exhibit "A" is the Affidavit of Theodore J. Bednarek.

ANSWER: OTI admits that a document entitled "Affidavit" is attached to the Complaint as Exhibit A. OTI denies the allegations of Paragraph 14 to the extent they are inconsistent with the terms in Exhibit A.

WHEREFORE, defendant, OSTEOIMPLANT TECHNOLOGY, INC., requests that this Court enter judgment in its favor, and against plaintiff, NOLA C. VAN DUYNE, on Count I of her Complaint, for court costs and for such other relief that this Court deems just and proper.

COUNT II / NEGLIGENCE

1. That the Plaintiff, NOLA C. VAN DUYNE, presently resides at 619 Van Buren Street, Wilmington, Will County, Illinois.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 1, and therefore denies the same.

2. That the Plaintiff, LEO VAN DUYNE, is the husband of the Plaintiff, NOLA C. VAN DUYNE, and he presently resides at 619 Van Buren Street, Wilmington, Will County, Illinois.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 2, and therefore denies the same.

3. That the Defendant, ENCORE MEDICAL, L.P., is a corporation with its principal place of business in Austin, Texas. This corporation manufactures, designs, assembles and sells orthopedic medical devices.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 3, and therefore denies the same.

4. That the Defendant, ENCORE ORTHOPEDICS, INC., is a corporation with its principal place of business in Austin, Texas. This corporation manufactures, designs, assembles and sells orthopedic medical devices.

ANSWER: Upon information and belief, OTI admits the allegations in Paragraph 4.

5. That the Defendant, OSTEOIMPLANT TECHNOLOGY, INC., is a corporation with its principal place of business in Baltimore, Maryland. This corporation manufactures, designs, assembles and sells orthopedic medical devices.

ANSWER: Defendant denies the allegations contained in Paragraph 5.

6. On or before November 20, 2002, the Defendants, ENCORE MEDICAL, L.P.; ENCORE ORTHOPEDICS, INC.; and OSTEOIMPLANT TECHNOLOGY, INC., acting through their agents and employees, designed, assembled, manufactured, sold and distributed an Alfa II total hip prosthesis. This was a fifty millimeter cup with three spikes and porous coating, with a twenty-eight millimeter lock polyliner with a ten degree lateral lip, a size two medial aspect stem with a thirty-eight millimeter neck.

ANSWER: OTI admits the allegations of Paragraph 6, as it relates to OTI. OTI has insufficient information or knowledge as to the truth of the remaining allegations in Paragraph 6 not directed to it, and therefore denies the same.

7. On or before November 20, 2002, the Defendants, ENCORE MEDICAL, L.P.; ENCORE ORTHOPEDICS, INC.; and OSTEOIMPLANT TECHNOLOGY, INC., acting through their agents and employees, sold or distributed to Oak Orthopedics in Kankakee, Illinois, the above mentioned Alfa 11 total hip prosthesis.

ANSWER: OTI has insufficient knowledge as to the truth of the allegations in Paragraph 7, and therefore denies the same.

8. On November 20, 2002, Oak Orthopedics, acting through its agent or employee, Milton J. Smit, M.D., implanted the Alfa 11 total hip prosthesis in NOLA C VAN DUYNE.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 8, and therefore denies the same.

9. On August 6, 2005, NOLA C VAN DUYNE, was sitting on a stool, at a table, and she noticed that she could not move her right hip. She also noticed that her right foot was externally rotated. She immediately went to a local hospital, where x-rays were taken. The x-rays showed a disassociation between the femoral neck component and the stem component and the Alfa II hip prosthesis.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 9, and therefore denies the same.

10. On August 10, 2005, Dr Milton Smith, of Oak Orthopedics, performed surgery on NOLA C. VAN DUYNE. During the surgery, Dr Smit confirmed that the Alfa II hip prosthesis failed and that the neck had disassociated from the stem segment. Dr Smit performed a right total hip revision on NOLA C VAN DUYNE on August 10, 2005.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 10, and therefore denies the same.

11. The first time NOLA C VAN DUYNE discovered anything wrong with her Alfa II hip prosthesis was on August 6, 2005, when she experienced the pain in her right hip and notice that her right foot had been externally rotated.

ANSWER: OTI has insufficient information or knowledge as to the truth of the allegations in Paragraph 11, and therefore denies the same.

12. That Defendants, ENCORE MEDICAL, L.P.; ENCORE ORTHOPEDICS, INC ; and OSTEOIMPLANT TECHNOLOGY, INC,, acting through their agents and employees were under a duty to design, assemble, manufacture and sell medical hip prosthetic devices consistent with industry standards for design, manufacture, assembly and sale of medical/orthopedic hip products.

ANSWER: OTI states the allegations in this Paragraph 12 call for a legal conclusion to which no response is required. To the extent that a response is required, OTI states that to the extent Paragraph 12 seeks to impose duties on OTI that are greater than those imposed by law, OTI denies those allegations and states that it has only such duties as are imposed by law. OTI has insufficient information or

knowledge as to the truth of the remaining allegations in Paragraph 12 not directed to it, and therefore denies the same.

13. That the Defendants, ENCORE MEDICAL, L.P.; ENCORE ORTHOPEDICS, INC.; and OSTEOIMPLANT TECHNOLOGY, INC., acting through their agents and employees, violated the above mentioned duty and they were careless and negligent in the following ways:

- a. Sold to Oak Orthopedics a defective Alfa II hip prosthetic implant, which was ultimately sold to and implanted in the Plaintiff, NOLA C. VAN DUYNE.
- b. Failed to perform proper testing on the Alfa II prosthesis hip system, especially the connecting parts between the neck and stem segment, prior to allowing this system to leave their control
- c. Knew or should have known that the Alfa II prosthesis hip system, especially the parts between the neck and the stem segment were defective and that these parts would not and could not withstand the everyday stresses, while the device was implanted in NOLA C VAN DUYNE's hip.

ANSWER: OTI denies the allegations in Paragraph 13, including its subparts (a) through (c). OTI has insufficient information or knowledge as to the truth of the remaining allegations in Paragraph 13 not directed to it, and therefore denies the same.

14. That as a direct and proximate result of the foregoing, NOLA C VAN DUYNE, was injured, she has incurred and will continue to incur unnecessary medical bills.. She experienced and will continue to experience pain and suffering.. She underwent unnecessary surgery.

ANSWER: OTI denies the allegations in Paragraph 14.

15. Attached hereto and made a part hereof, and incorporated herein as Exhibit "A" is the Affidavit o Theodore J. Bednarek.

ANSWER: OTI admits that a document entitled "Affidavit" is attached to the Complaint as Exhibit A. OTI denies the allegations of Paragraph 15 to the extent they are inconsistent with the terms in Exhibit A.

WHEREFORE, defendant, OSTEOIMPLANT TECHNOLOGY, INC., requests that this Court enter judgment in its favor, and against plaintiff, NOLA C. VAN DUYNE, on Count II of her Complaint, for court costs and for such other relief that this Court deems just and proper.

COUNT III / LOSS OF CONSORTSIM FOR LEO VAN DUYNE

NOW COMES, the Plaintiff, Leo Van Duyne, by and through his attorney, THEODORE J. BEDNAREK & ASSOCIATES, and for his complaint against the Defendants, ENCORE, MEDICAL, L.P.; ENCORE ORTHOPEDICS, INC.; and OSTEOIMPLANT TECHNOLOGY, INC., repeats and realleges paragraph 1 through 15 of Counts II as and for this Count III.

As a result of the above mentioned negligence Plaintiff, LEO VAN DUYNE, lost the love affection and intimacy of his wife, NORA C. VAN DUYNE, for a substantial time after August 6, 2005.

ANSWER: OTI repeats and realleges its responses to Paragraphs 1 through 15 of Count II as its response to Paragraphs 1 through 15 of this Count III. Further answering, OTI denies the remaining allegations in this Count III.

WHEREFORE, defendant, OSTEOIMPLANT TECHNOLOGY, INC., requests that this Court enter judgment in its favor, and against plaintiff, LEO VAN DUYNE, on Count III of his Complaint, for court costs and for such other relief that this Court deems just and proper.

COUNT IV

OTI makes no answer to the allegations in Count IV as they are not directed to it. To the extent that any allegation is construed to be directed to it, OTI denies the same.

AFFIRMATIVE DEFENSES

Defendant, OSTEOIMPLANT TECHNOLOGY, INC. ("OTI"), by its attorneys, ARNSTEIN & LEHR LLP, pleading in the alternative and without prejudice to its Answer to Plaintiffs' Complaint, and for its Affirmative Defenses against Plaintiffs, states as follows:

1. Plaintiff's Complaint fails to state a claim upon which relief can be granted;
2. Plaintiff's claims are barred by the applicable statute of limitations;
3. Plaintiff has failed to join all proper parties and has misjoined parties to this action;
4. Plaintiff, NOLA C. VAN DUYNE, at the time of the events in question, was fully aware of the conditions existing, any risks inherent therein, and knowingly, willingly and voluntarily assumed the risk of conditions present and the dangers inherent therein;
5. Plaintiff, NOLA C. VAN DUYNE's injuries and damages, if any, resulted from an intervening or superseding cause and/or causes, and any action on the part of OTI was not the proximate cause of such alleged injuries;
6. Plaintiffs' claims are barred because if Plaintiffs sustained injuries or damages, which is denied, those injuries and damages were not proximately caused by any act or omission of OTI;
7. Plaintiff NOLA C. VAN DUYNE's alleged injuries and damages were caused or contributed, directly or proximately, in whole or in part, by the negligent fault, acts, breaches, omissions, or other conduct of Plaintiff, or others that are attributable to her, so that any recovery by Plaintiff must be diminished by the degree of such conduct which is attributed to Plaintiff;

8. Plaintiff NOLA C. VAN DUYNE's alleged injuries and damages were caused or contributed, directly or proximately, in whole or in part, by the negligent fault, acts, breaches, omissions, or other conduct of other persons, firms and/or entities not specifically named in the Complaint and for which OTI is not responsible;

9. Plaintiff NOLA C. VAN DUYNE's alleged injuries and damages, if any, were the result of unavoidable circumstances which could not have been prevented by anyone.

10. Plaintiffs' claims are barred because OTI complied with all applicable federal and state statutes, the requirements and regulations of the United States Food & Drug Administration ("FDA"), pertinent industry standards and specifications, and all statutes and/or regulations promulgated by local government agencies;

11. Plaintiffs' Complaint fails to state a claim upon which relief can be granted, because the federal government has preempted the field of law applicable to the product alleged to have caused Plaintiff's alleged injuries and damages, including but not limited to, preemption, in whole or in part, by the Federal Food, Drug and Cosmetic Act, and the granting of the relief requested in Plaintiff's Complaint would impede, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause of the United States Constitution (Art. VI, Clause 2);

12. Plaintiffs' Complaint fails to state a claim upon which relief can be granted, because there is no private right of action under the Federal Food, Drug and Cosmetic Act;

13. At all relevant times, adequate warnings, information and instructions were provided for the product, pursuant to generally recognized prevailing standards in existence at the time;

14. Plaintiffs' claims are barred because there is no privity between Plaintiff and OTI;

15. In the event that OTI is adjudged liable to Plaintiffs, which liability is expressly denied, OTI is entitled to a percentage contribution of the total liability from any parties also adjudged liable in accordance with principles of equitable indemnity and comparative contribution;

16. In the event that OTI is adjudged liable to Plaintiffs, which liability is expressly denied, OTI is entitled to a set-off for the total of all amounts paid to Plaintiffs from any collateral sources, and any recovery by Plaintiffs must be reduced or offset by amounts Plaintiffs has received or will receive from others for the same injuries claimed in their lawsuit; and,

17. Plaintiffs may have failed to exercise ordinary care, reasonable care and/or diligence to mitigate damages, if any.

WHEREFORE, defendant, OSTEOIMPLANT TECHNOLOGY, INC., requests that this Court dismiss the Complaint of plaintiffs, NOLA C. VAN DUYNE and LEO VAN DUYNE, or alternatively enter judgment in its favor and against plaintiffs on their Complaint, for court costs and for such other relief that this Court deems just and proper.

OSTEOIMPLANT TECHNOLOGY, INC.,

By: s/ Sharilee K. Smentek
One of its Attorneys

David S. Waxman (ARDC # 6191045)
Sharilee K. Smentek (ARDC # 6277773)
ARNSTEIN & LEHR LLP
120 South Riverside Plaza, Suite 1200
Chicago, Illinois 60606
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CERTIFICATE OF SERVICE

Sharilee K. Smentek, an attorney, certifies that she served copies of **OTI's Answer and Affirmative Defenses to Plaintiffs' Complaint** on the following parties:

Wayne B. Giampietro
Kevin J. Berrill
STITT, KLEIN, DADAY, ARETOS & GIAMPIETRO, LLC
121 S. Silke, Suite 500
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Jeffery Singer
Paige Norian
SEGAL McCAMBRIDGE SINGER & MAHONEY, LTD.
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via e-mail notification served by the CM/ECF system on July 7, 2008.

s/ Sharilee K. Smentek